DIAMETRICS MEDICAL

2658 Patton Road Saint Paul MN 55113-1136 USA Phone: 651/639.8035 Fax: 651/639.8549

JAN 2 8 2002

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA1990 and 21 CFR 807.92.

The assigned 510(k) number is: K013938 .

Submitter:

Diametrics Medical, Inc.
2658 Patton Rd
Roseville, MN 55113
Phone: (651) 638-1250
Fax: (651) 638-1060
Contact Person: Nancy Ring

Establishment Registration Number: 2183953

Summary Prepared on: November 27, 2001

Identification of Device:

Device Name:	Lactate Cartridge
Proprietary Name:	IRMA® SL Blood Analysis System Lactate Cartridge
Common Name:	Lactic Acid Test System
Classification Name:	Acid, Lactic, Enzymatic Method
Device Classification:	Class I
Regulation Number:	21 CFR 862.1450
Panel:	Chemistry (75)
Product Code:	KHP

Name of Predicate Device: YSI Model 2300 Stat Plus.

Predicate Device 510(k) Number: K891480

Predicate Device Product Code: 75 CGA

Substantial Equivalence Claim
The IRMA® SL Blood Analysis System GL Cartridge is substantially equivalent in method, intended use and clinical performance to the currently marketed YSI Model 2300 Stat Plus.

Device Description
The IRMA® SL Blood Analysis System Lactate Cartridge is for use with the IRMA®Blood Analysis System. The Lactate cartridge is a single use, disposable cartridge, for the in vitro measurement of lactate in whole blood.

Samples are introduced via syringe or capillary injections with the IRMA® Capillary Collection Device. The lactate sensor uses an amperometric electrode along with a reference electrode that measures the lactate oxidase reaction. The IRMA® sensors are calibrated prior to each test using a calibrant packaged with the sensors. Calibration of the cartridge is completed when information determined at the factory for each lot of cartridges is combined with measurements taken during the calibration process. Factory derived calibration parameters are input into the analyzer by calibration code entry.

Throughout the calibration and analysis process, signals from the sensors are analyzed. If any abnormal conditions are detected, an error message is generated and the test will be terminated. If there are no abnormal conditions, then the sample results (measured and calculated) are displayed after successful calibration and analysis. In addition, the user has the option to print a hard copy of the results.

Intended Use
The lactate sensor is intended for professional and point of care use with the IRMA® Blood Analysis System for the direct measurement of lactate, in human whole blood. The Lactate Cartridge and the IRMA® Blood Analysis System are for in vitro diagnostic use.

Indications for Use
Lactate evaluates the acid-base status and is used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Summary of Technological Characteristics
The following table shows comparison to the predicate device.

	IRMA®	YSI Model 2300 Stat Plus
Detection Method	Lactate Oxidase	Lactate Oxidase
Analytes measured	Lactate	Glucose, Lactate
Measuring Range	Lactate: 2.7 – 180.2 mg/dL (0.30 – 20.00 mmol/L)	Lactate: 0-135 mg/dL (0-15 mmol/L)
Operating Temp.	12-30°C (59-86°F)	15.0-35°C (59-95°F)
Operating Humidity	0-80%	10-90%* *Non-condensing
Sample	Whole blood 0.2 - 3.0 mL, from syringe 0.125 mL from capillary collection device	Lactate: Whole Blood, serum, or plasma 25 µL aspirated volume
Power	7.2 V NiCAD rechargeable battery or AC adapter	120 VAC 240 VAC
Reagents	Supplied in self-contained disposable cartridge	Supplied in a Buffer Concentrate (YSI 2357) that is added to water and a liquid Calibrator solution (YSI 2747)
Weight	5 lbs.	25 lbs.
Results	Display and printer on board	Display and printer on board
Calibration	Automatic with each sample	Self calibrates every 5 samples or 15 minutes, or after a calibration shift of 2% or greater, or after a sample chamber temperature drift of more than 1° C.
Sensors	Disposable single-use	Reusable sensor probes

Summary of Performance Data:

Accuracy:

Analyte	n	Range evaluated	Slope	Intercept	r	Sy.x
Lactate	30	1 - 250 mg/dl	0.97	1.87	0.991	9.11

Precision

Level	N	IRMA Lactate Mean (mg/dl)	IRMA Lactate Total Precision sd	IRMA Lactate Total Precision %CV
1	59	7.02	1.08	15.3
2	59	80.11	4.10	5.1
3	59	132.8	8.68	6.5
4	58	177.5	16.0	9.0

Linearity:

Analyte	n	Display Range	Assessment
Lactate	20	2.7-180 mg/dl	Linear

Conclusions:

The data demonstrates that the Lactate Cartridge is as safe, effective and performs as well as the legally marketed predicate device to which equivalence is claimed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 8 2002

Ms. Nancy Ring
QA/RA Manager
Diametrics Medical, Inc.
2658 Patton Road
Saint Paul, MN 55113-1136

Re: k013938
Trade/Device Name: Diametrics Medical, Inc, IRMA® Blood Analysis System
Lactate Cartridge
Regulation Number: 21 CFR 862.1450
Regulation Name: Lactic Acid test system
Regulatory Class: Class I
Product Code: KHP
Dated: November 27, 2001
Received: November 28, 2001

Dear Ms. Ring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

Intended Use

The lactate sensor is intended for professional and point of care use with the IRMA® Blood Analysis System for the direct measurement of lactate, in human whole blood. The Lactate Cartridge and the IRMA® Blood Analysis System are for in vitro diagnostic use.

Indications for Use

Lactate evaluates the acid-base status and is used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

(Please DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013938

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)